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April 2, 2015

Via Federal Express
TSCA Confidential Business Information Center (7407M)
EPA East - Room 6428 Attn: Section 8(e)
U.S. Environmental Protection Agency
1201 Constitution Avenue, NW
Washington, DC 20004-3302

Subject: Notice in Accordance with TSCA Section 8(e): Results of a Test Study in male and female Wistar Rats with an experimental pesticide

Dear Section 8(e) Coordinator:

[redacted] is submitting results of a Test Study in Male and Female Wistar Rats [Crl:WI(HAN)] with [redacted], conducted by [redacted]. The test substance is an experimental pesticide.

The test substance was administered via the diet to groups of 5 Wistar rats for a maximum of 14 days. The concentration levels were 150 and 500 ppm.

During the administration period all animals were examined for clinical signs of toxicity. At the end all animals were sacrificed and clinical pathology as well as pathology parameters where examined (histopathological examinations only in control and high dose group).

The following is a summary of the most relevant results:

Test group 2 (500 ppm)

- Piloerection in 1/5 females
- Food consumption significantly decreased over the entire study period (about -24.4% for males; about -22.2% for females)
- Bodyweight significantly decreased in males (up to -16.9%) and females (up to -14.6%)
- Bodyweight change significantly decreased (about -45.8% for males; about -60.9% for females)
- Decreased concentration of red blood cells, hematocrit, hemoglobin, platelets, globulins and cholesterol
- Decreased values for reticulocytes in males
- Decreased concentration of platelets and prothrombin time (Hepato Quick's test) in females
- Decreased terminal body weight in male (-17%) and female (-14%) animals
- Increased relative liver weights in male (26%) and female (20%) animals
- Increased relative kidney weights in male (15%) and female (23%) animals
- Increased relative weights of adrenal glands (38%) in male animals
- Necrosis (minimal to mild) of tubular epithelial cells in kidneys (1/5 male and all female animals)

- Vacuolar degeneration of tubular epithelial cells (minimal to moderate) in kidneys (all male and 4/5 female animals)
- Increased severity of basophilic tubules in kidneys of male and female animals (mild to moderate and bilateral in treated animals, minimal and mostly unilateral in controls)
- Minimal centrilobular hepatocellular hypertrophy in liver of 4/5 male and 1/5 female animals
- Single cell necrosis/apoptosis (minimal to mild) in pancreas of all male and female animals
- Decreased extramedullary hematopoiesis in the spleen of male animals
- Unilateral neutrophilic inflammation of the cornea (2/5 female animals)
- Unilateral erosion of the cornea (1/5 female animal)

Test group 1 (150 ppm)

- Decreased prothrombin time (Hepato Quick's test) in females
- Increased relative kidney weights in male (+14%) and female (+13%) animals

[redacted] understands that reporting of results from this study under TSCA 8(e) is in accordance with EPA's policy.

Please note that a confidential version of this letter is enclosed, treating the chemical identity and company identity as Confidential Business Information.

A Confidentiality Substantiation Questionnaire is being submitted.

Sincerely,